

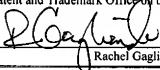
UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Alan Shluzas et al. Confirmation No.: 3377
Serial No.: 10/658,736 Examiner: Nicholas W. Woodall
Filing Date: September 9, 2003 Group Art Unit: 3775
Docket No.: 1291.1138101 Customer No.: 33469
For: METHOD AND APPARATUSES FOR TREATING THE SPINE THROUGH
AN ACCESS DEVICE

Mail Stop Appeal
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW**CERTIFICATE FOR ELECTRONIC TRANSMISSION:**

The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 8th day of September 2009.

By  _____
Rachel Gagliardi

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a prima facie rejection. Claims 20-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Mathews in view of Haider, Foley and Davison. The Examiner acknowledges that Mathews teaches a method in which a plate/screw fixation system is attached to the vertebra and placed above the muscles and below the skin. The Examiner appears to be asserting that because the general outcome of Mathews (attaching a plate/screw fixation system to vertebra to stabilize adjacent vertebra) is similar to the general outcome of Haider (attaching a rod/screw fixation system), the two systems are functional equivalents and it would have been obvious to substitute one element of a system for the other. The Examiner appears to be considering the plate of Mathews and rod of Haider as the only differences between the two systems and thus functionally equivalent. Applicants respectfully disagree. Mathews specifically teaches a suprafascial fixation system that is designed to be placed above the vertebra and muscles, as clearly shown in FIG. 1, while Haider teaches a rod-based system that is attached at the level of the vertebra, under the muscle, as shown in FIG. 1. Further, Mathews teaches, "a technique which further permits subcutaneous

removal of the temporarily implanted hardware in an out-patient procedure.” See column 3, lines 10-12. Mathews also teaches:

Most significantly, the hardware resides within the suprafascial subcutaneous space 25 so that destruction of muscle tissue is not required. With this method, patient morbidity rates are reduced, while healing rates are improved. Since the fixation hardware resides above the muscle layer, removal can be conducted in an out-patient procedure under a local anesthetic.

See column 7, lines 41-47. The function of the Mathews system appears to be to temporarily connect two vertebra during a fusion, and to avoid muscle damage and allow for easy removal. Haider, however, appears to teach a system in which a rod is connected to multiple levels of vertebra at the level of the vertebra, under the muscles. The two systems are thus structurally and functionally distinct and there is no motivation or reasonable expectation of success in substituting one for the other. The Examiner asserts that it would have been obvious to one of ordinary skill in the art to perform the method of Mathews further including performing a multi-level fixation procedure in view of Haider, performing a decompression procedure in view of Foley, and inserting an access device in view of Davison in order to fix multiple joints of the spine. Mathews teaches away from the asserted combination.

Mathews teaches:

The fixation process is suprafascial that is above the muscle fascia, but subcutaneous, that is beneath the surface of the skin. Thus, none of the muscle tissue is destroyed and the subcutaneous nature of the procedure greatly decreases the risk of pin tract secretions or infections, or the potential of osteomyelitis.

See column 2, lines 4-9. Mathews thus specifically teaches a subcutaneous method of installing fixation hardware above the muscle layer. As seen in the above quotes, Mathews provides advantages for inserting the fixation system above the muscle. Applicants submit that Mathews teaches away from any modification of his method to include the multi-level polyaxial screw system of Haider or the access device of Davison et al. Haider appears to teach a fixation system in which screws and rods are inserted to the level of the pedicle, as shown in FIG. 1. Haider specifically teaches, “[t]he screw assembly of the present invention when secured in place does not protrude into the surrounding soft tissue”; see column 3, lines 50-52 and FIG. 1. Haider’s teaching of a fixation system installed directly on the vertebra appears to be in direct contradiction to the specific method steps of installing a fixation system above the muscle, as

taught by Mathews. Further, the system of Mathews appears to function by temporarily connecting vertebra between the muscle and skin, allowing for easy removal, while the Haider multi-level fixation system is at the level of the vertebra. There is no reasonable expectation of success in performing the multi-level fixation using a rod/screw system of Haider in the method of Mathews, or vice versa. Each method appears to require the specific elements and method steps taught in the references. While the generic outcome of connecting vertebra may be similar, the specific method steps and elements used in the method steps are significantly different, rendering the methods distinct and not merely functional equivalents, as asserted by the Examiner.

The Examiner asserts, "both Mathews and Davison disclose a method of minimally invasively performing a spinal procedure" thus Mathews does not teach away from the proposed combination. Applicants respectfully disagree. Davison et al. appears to teach inserting an expandable device into an incision and expanding a distal portion of the device to provide "a significantly larger working area for the surgeon inside the body 130 within the confines of the cannula." See paragraphs 0031-0035 and FIGS. 1 and 5. Davison et al. appear to teach a device for expanding a surgical incision. Mathews specifically teaches a surgical procedure in which screws and plates or rods are inserted beneath the skin but above the muscle. Mathews teaches:

After the guide pin insertion process is complete, an incision is made at the guide pin insertion site, which, in one specific embodiment, is about 2.0 cm. in length. Then, using pick-ups and Metzenbaum scissors, subcutaneous tissue is dissected suprafascially. Metzenbaum scissors are also used to dissect the suprafascial subcutaneous tissues from the ipsilateral pin across the midline to the contralateral guide pin. Dissection of this tissue provides space for connection of pedicle screws in subsequent steps of the method.

See column 5, lines 34-42. Mathews thus teaches a specific method of dissecting the suprafascial space for connecting pedicle screws and a plate. Mathews also teaches inserting a three component tissue dilator system to create a path for inserting the self-tapping bone screw. See column 5, lines 43-59. Mathews thus already teaches specific method steps for achieving the desired suprafascial dissection and screw insertion. The access device of Davison et al. would not appear to be suitable for performing these specific method steps of Mathews. Further, because Mathews already teaches devices and methods for achieving the desired suprafascial dissection necessary for their specific method, there is no motivation for one of ordinary skill in

the art to go against the teachings of Mathews to insert the screw and rod assembly of Haider or use the access device of Davison et al.

Applicants submit that there is no reasonable expectation of success for one of ordinary skill in the art to modify the method of Mathews to include the screw system of Haider and use the access device of Davison et al. because doing so would appear to destroy the functionality and advantages of the Mathews system and method. The Examiner asserts that because both Mathews and Haider teach methods of treating the spine including the use of a spinal fixation system it would have been obvious to one having ordinary skill in the art to substitute one spinal fixation system with the other in order to achieve the predictable results of immobilizing the spine during fusion of the spinal segments. Applicants respectfully disagree. As discussed above, Mathews teaches a specific screw and plate system designed for insertion suprafascially, under the skin but over the muscle. The screw and rod system of Haider appears to be designed to be inserted at the level of the pedicle, under the muscle. The fixation systems of Mathews and Haider thus do not appear to be interchangeable, and one of ordinary skill in the art would have no reasonable expectation of success in attempting to use the screws and rods of Haider in the suprafascial fixation method of Mathews. Foley does not appear to provide any motivation or expectation of success in modifying Mathews as suggested by the Examiner.

MPEP 2143.01 III states:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless **>the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007)

Applicants submit that the results of somehow combining the different methods of Mathews and Haider would not have been predictable, thus the mere fact that the references might, somehow, be combined is not a proper basis for obviousness.

Mathews appears to teach away from any combination with Haider, Foley, and Davison et al., and further, there is no reasonable expectation of success. The only suggestion to combine the references appears to be in the instant specification, which is an improper basis for obviousness. The rejection is thus an error. Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Alan Shluzas et al.

By their Attorney,

Date: 9/8/09


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